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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY,)
JANIS KATE TURNER, and)
JEDIDJAH DE VRIES,)
Plaintiffs,)
v.)
UNITED STATES DEPARTMENT OF ENERGY,)
NATIONAL NUCLEAR SECURITY)
ADMINISTRATION, LAWRENCE LIVERMORE)
NATIONAL LABORATORY,)
Defendants.)

Case No. 08-cv-1372-SBA

**DEFENDANTS' OPPOSITION
TO PLAINTIFFS' SECOND
MOTION FOR LEAVE TO
FILE A SUPPLEMENTAL
BRIEF**

I. INTRODUCTION

Before the Court is Plaintiffs' second motion to file a supplemental brief in support of their motion for a preliminary injunction against operation of the Biosafety Level-3 ("BSL") facility at Lawrence Livermore National Laboratory ("LLNL") at Livermore, California. Dkt. No. 47. In their motion, Plaintiffs seek the admission – as extra-record evidence “necessary to determine whether the agency has considered all relevant factors and has explained its decision,” – of a draft Environmental Impact Statement (“EIS”) issued in June 2008 by the Department of Homeland Security (“DHS”) for a proposed National Bio and Agro-Defense Facility (“NBAF”). As set forth below, Plaintiffs' motion must be denied. First, Plaintiffs' motion fails because the proffered draft EIS was not available to the DOE at the time the BSL-3 decision was made, and post-decision materials are not admissible extra-record evidence of factors an agency allegedly failed to consider. Second, assuming *arguendo*, that post-decision materials are admissible, the draft EIS for the NBAF does not demonstrate that the DOE failed to consider any relevant factors or was otherwise arbitrary or capricious in issuing the EA for the LLNL BSL-3 facility.

II. LEGAL STANDARDS

Judicial review of the adequacy of the BSL-3 EA prepared by the DOE is governed by the Administrative Procedure Act (“APA”), 5 U.S.C. § 706. Under the APA, a court is to review an agency's decision on the basis of the administrative record that existed before the agency at the time the decision was made. Both the Supreme Court and the Ninth Circuit have emphasized that “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” Camp v. Pitts, 411 U.S. 138, 142 (1973). See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985); Southwest Ctr. for Biological Diversity v. U.S. Forest Serv., 100 F.3d 1443, 1450 (9th Cir. 1996). As the Ninth Circuit has held, “[t]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.” Friends of the Earth v. Hintz, 800 F.2d 822, 829 (9th Cir. 1986) (quoting Florida Power & Light Co., 470 U.S. at 743-44); see Southwest Ctr. for Biological Diversity, 100 F.3d at 1450-51.

1 If the record is not sufficient to judge the agency's decision, the decision should be
2 remanded. Courts are not to consider information "that was not available at the time the
3 [Agency] made its decision." Airport Cmty. Coalition v. Graves, 280 F. Supp. 2d 1207, 1213
4 (W.D. Wash. 2003) (noting that consideration of "new information represents 'Monday morning
5 quarterbacking.'").

6 The Ninth Circuit allows a reviewing court to consider extra-record materials in APA
7 cases only under four narrow exceptions: "(1) if necessary to determine 'whether the agency has
8 considered all relevant factors and explained its decision,' (2) 'when the agency has relied on
9 documents not in the record,' (3) 'when supplementing the record is necessary to explain
10 technical terms or complex subject matter,'" or (4) "'when plaintiffs make a showing of agency
11 bad faith.'" Inland Empire Public Lands Council v. Glickman, 88 F.3d 697, 703-04 (9th Cir.
12 1996) (quoting Friends of the Payette v. Horseshoe Bend Hydroelectric Co., 988 F.2d 989, 997
13 (9th Cir. 1993) (per curiam) and National Audubon Soc'y v. U.S. Forest Serv., 46 F.3d 1437,
14 1447 n.9 (9th Cir. 1993)).

15 Mere allegations that the court should look beyond the administrative record to consider
16 material falling into one of the four exceptions are not sufficient; a plaintiff must first make a
17 showing that the record is inadequate. Animal Defense Council v. Hodel, 840 F.2d 1432, 1437
18 (9th Cir. 1988) ("The [plaintiff] makes no showing that the district court *needed* to go outside the
19 administrative record to determine whether the [agency] ignored information") (emphasis
20 added).

21 **III. ARGUMENT**

22 **A. The Draft EIS for the NBAF Does Not Fall Within Any Exception to Record** 23 **Review.**

24 As noted above, the Ninth Circuit recognizes four limited exceptions to the rule that the
25 review of an agency action is limited to the administrative record. Plaintiffs assert that the
26 NBAF draft EIS is admissible under the exception for materials necessary to determine "whether
27 the agency has considered all relevant factors and explained its decision." Pls.' 2nd Mot. for
28 Leave at 3. This claim fails at the threshold because the exception allowing admission of extra-

1 record material to determine whether the agency has considered all relevant factors and
2 explained its decision, “only applies to information available at the time, not post-decisional
3 information.” Rock Creek Alliance v. U.S. Fish and Wildlife Serv., 390 F. Supp. 2d 993, 1002
4 (D. Mont. 2005) (denying motion to submit extra-record material unavailable when the decision
5 was made).

6 As the court in Airport Communities Coalition, 280 F. Supp. 2d at 1213, explained in
7 striking extra-record material unavailable to the agency when the decision was made:

8 Here the extra-record information represents new information that was not
9 available at the time the [agency] made its decision. If the information had been
10 available within that time frame, the court could then use that information to
11 determine whether the [agency] acted arbitrarily and capriciously in not
12 considering that information as a relevant factor If the court were to consider
13 this new information in an arbitrary and capricious analysis the court would
14 effectively transform that analysis into a *de novo* review, a level of review for
15 which this court is not authorized.

16 Here, the final revised EA for the LLNL BSL-3 facility was issued on January 25, 2008.
17 Defs’ Exh. 5 [Dkt. No. 12] at ¶ 3. The draft EIS for NBAF was issued six months later, in June
18 2008. The draft EIS for the NBAF was therefore not available for consideration by the DOE
19 during the decisionmaking process for the LLNL EA, and consequently does not fall within any
20 exception to record review. For this reason alone, Plaintiffs’ motion to file a supplemental brief
21 should be denied.

22 **B. Even if Post-Decision Documents are Admissible, the Draft EIS for NBAF
23 Does Not Show DOE Failed to Consider Relevant Factors or Explain its
24 Decision.**

25 Even if the Court determines that documents unavailable to the agency at the time the
26 challenged decision was made may fall within an exception to record review, the NBAF draft
27 EIS does not bear on whether the DOE considered all relevant factors and explained its decision.

28 **1. The Proposed NBAF and the LLNL BSL-3 are Not Comparable
Facilities.**

Plaintiffs first assert that because of the “structural and operational similarities” and “like
potential for significant impacts,” of the two facilities, the fact that an EIS was prepared for the

1 proposed NBAF suggests an EIS should also have been prepared for the LLNL BSL-3.^{1/} This
 2 claim fails.

3 There is little structural commonality between the two facilities. The proposed NBAF
 4 facility is a complex composed of six buildings encompassing 500,000 to 520,000 square feet
 5 and requiring 30-acres of open land. DEIS at ES-3 and 1-2.^{2/} In contrast, the LLNL BSL-3 is
 6 single 1,500 square foot building constructed on 1/4 quarter acre of land. FREA at 9. The
 7 proposed NBAF includes a staff of 250-350 people, while the LLNL BSL-3 lab has a staff of six.
 8 Compare DEIS at 1-2 with FREA at 9. NBAF could house 200 to 300 large animals at any
 9 given time, including cattle, swine and sheep, while the BSL-3 has the capacity of contain a
 10 maximum of 100 small rodents. Compare DEIS at 2-1 with FREA at 16.

11 Obviously, two such vastly different facilities will have substantially different impacts.
 12 For example, the draft EIS for NBAF anticipates that the facility will generate 25 to 30 million
 13 gallons of wastewater annually, while the LLNL BSL-3 is anticipated to generate 10,000 gallons.
 14 Compare DEIS at ES-7 with FREA at 24. Moreover the NBAF, which would be similar in size
 15 to a 400 bed hospital or 1,600 student high school, would have unavoidable adverse visual
 16 impacts. DEIS at ES-7. In contrast, the LLNL BSL-3 occupies a former parking lot and has “no
 17 visual issues.” FREA at 31. These differences easily justify the preparation of an EIS in one
 18 case and an EA in the other.

19 The operational differences between the two facilities also belie Plaintiffs’ suggestion
 20 that the NABF draft EIS demonstrates an EIS should have been prepared for the LLNL BSL-3.

21 _____
 22 ^{1/} Plaintiffs attempt in passing to resurrect their argument that DOE should prepare an EIS
 23 for the LLNL BSL-3 facility because the DOE has determined to prepare an EIS for a BSL-3
 24 facility at the Los Alamos Nuclear Laboratory in New Mexico. Pls.’ 2d Supp. Br. at 7, n. 4. As
 25 explained in Defendants’ Opposition to Plaintiffs’ Motion for a Preliminary Injunction, this
 26 claim fails because the circumstances surrounding the preparation of an EIS for the Los Alamos
 27 facility are unrelated to the LLNL facility. Defs’ Opp. to Plfs.’ Mot. for Prelim. Inj. [Dkt. No.
 28 11] at 16.

^{2/} Defendants will cite to the Draft EIS for the NBAF, which is Exhibit 30 to Docket
 Numbers 47-49, as “DEIS” followed by the appropriate page. Defendants will cite the Final
 Revised EA for the LLNL BSL-3, which is Exhibit 1 to Dkt. No. 12, as “FREA” followed by
 the appropriate page.

1 Most critically, the NBAF will include between 55,000 and 57,000 square feet designed for
2 BSL-4 research. DEIS at 1-2 (“Approximately 11% of the 500,000 to 520,000-square-foot
3 NBAF would be designed for BSL-4 research...”). Unlike a BSL-3 facility, which utilizes
4 pathogens for which medical treatment is available, BSL-4 facilities are equipped to handle
5 “exotic pathogens that pose a high risk of life threatening disease in animals or humans through
6 the aerosol route and for which *there is no known vaccine or therapy*.” DEIS at 1-2 (emphasis
7 added). The presence of a BSL-4 capability alone is a critical difference between the two
8 facilities from a NEPA perspective. As explained in the NBAF draft EIS, while there are 1,356
9 BSL-3 facilities in 46 states, there are only 15 planned, under construction or operational BSL-4
10 labs nation-wide. DEIS at 1-3. Further, once constructed, the NBAF will be the *only* large
11 animal or livestock BSL-4 facility in the United States. DEIS at 1-3.

12 Plaintiffs’ suggestion that the two facilities will work with similar types and volumes of
13 pathogens is also baseless. Pls.’ 2nd Supp. Br. at 6. The NBAF is proposed to “enable basic and
14 advanced research, diagnostic testing and validation, countermeasure development (i.e. vaccines
15 and antiviral therapies), and diagnostic training for high-consequence livestock diseases with
16 potentially devastating impacts to U.S. agriculture and public health.” DEIS at ES-1. In pursuit
17 of that mission, NBAF will focus on zoonotic (capable of animal to human transmission) and
18 foreign animal diseases, including African swine fever, classical swine fever, foot and mouth
19 disease (“FMD”), Japanese encephalitis, Rift Valley fever and the Hendra and Nipah viruses,
20 DEIS at 1-2, none of which are expected to be cultured at the LLNL BSL-3. One of the principal
21 missions of the NBAF is development of a vaccine for FMD, which “is one of the most
22 devastating viral animal diseases affecting cloven hoofed animals.” DEIS at 1-4. The mission of
23 the LLNL BSL-3, in contrast, targets the reduction of the national threat from terrorism using
24 biological weapons and enhancement of public health capabilities. FREA at 6.

25 Plaintiffs also assert that the LLNL BSL-3 facility holds the same volume of pathogenic
26 material, “concentrated in a smaller area,” as NBAF. Pls.’ 2d Supp. Br. at 6, n. 3. This assertion
27 is incorrect. While the NBAF draft EIS does not explicitly set forth the maximum volume of
28 pathogenic material contained facility-wide, the quantity of material at risk used in the NBAF

1 accident analysis suggests a total facility volume of approximately **10,000 liters** –
2 approximately 200 times the capacity of the LLNL BSL-3 facility.^{3/} See Second Declaration of
3 Eric Gard (attached as Exhibit 1) at ¶ 4.

4 In sum, the NBAF facility is vastly larger than the LLNL BSL-3, works with a vastly
5 larger volume of different and higher risk pathogens than the LLNL BSL-3 facility, and serves a
6 different purpose than the BSL-3 facility. Moreover, rather than one of over a thousand similar
7 facilities nation-wide like the LLNL BSL-3, the NBAF is the first of its kind in the United
8 States. Under these circumstances, the decision to prepare an EIS for the NBAF does not
9 suggest that DOE was arbitrary and capricious in its decision not to prepare an EIS for the LLNL
10 BSL-3.

11 **2. The NBAF EIS Does Not Suggest the DOE Failed to Consider**
12 **Relevant Factors in Evaluating the Threat of Terrorist Activity.**

13 Plaintiffs assert that the draft EIS for the NBAF demonstrates that the DOE failed to take
14 a “hard look” at the potential environmental consequences of a terrorist attack at the proposed
15 BSL-3 facility. Pls.’ 2nd Mot. for Leave at 2. This claim fails.

16 First, as noted above, the NBAF and the LLNL BSL-3 are not comparable facilities, and
17 for that reason, the methodology utilized in one analysis does not suggest that the methodology
18 for the other analysis was inappropriate. For example, the LLNL BSL-3 adds one facility to a
19 baseline of hundreds of facilities nation-wide, and thus makes a negligible incremental change in
20 the risk of a terrorist attack. See FREA at 63. In contrast, the NBAF is the only facility of its
21 kind, and thus the difference between action and no-action is more likely meaningful.

22 However, to the extent that any comparison is appropriate, the terrorist analysis
23 conducted by the DHS for the NBAF is similar to that prepared for the LLNL BSL-3. For
24 example, the DHS developed a Threat and Risk Assessment (“TRA”) to “identify potential
25 vulnerabilities and weaknesses . . . and . . . recommend the most prudent measures to establish a
26 reasonable level of risk for the security of operations fo the NBAF.” DEIS at 3-430. Similarly,

27 ^{3/} Of course, it seems common sense that a facility with 300 times more square feet than
28 the LLNL BSL-3 would also contain a far higher volume of pathogens.

for the LLNL lab, the DOE developed a Biological Risk and Treat Assessment (“BRTA”) to “examine the potential vulnerabilities of the facility and its operations, and to mitigate risks.” FREA at 61. Both the TRA for NBAF and the LLNL EA consider threats of external acts and internal sabotage. Compare DEIS at 3-341 with FREA at 58. The NBAF TRA addressed mitigating threats through measures such as personnel security programs, contractor screening and monitoring, perimeter security procedures, behavior observation programs, inventory control, and coordination with local emergency response agencies. DEIS at 3-433. The EA for LLNL discussed analogous mechanisms for mitigating threats to the BSL-3 lab. See FREA at 63 (discussing “personnel security and screening programs”); id. at 61 (discussing perimeter security), id. at 65 (discussing personnel and inventory monitoring); id. at 60 (discussing coordination with local medical providers). In sum, the analytical approaches taken for the two documents are quite similar.^{4/}

Finally, with regard to the Ninth Circuit’s direction on remand, that the DOE “consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement,” the draft EIS for NBAF supports the DOE’s conclusion that the threat of terrorist activities does not have significant impacts requiring an EIS. Tri-Valley CARES v. Dep’t of Energy, No. 04-17252, 2006 WL 2971651, at *2 (9th Cir. Oct. 16, 2006). While the DHS has prepared an EIS, that analysis was not compelled by the impacts of potential terrorist activities. To the contrary, the draft EIS concludes that “[t]he evaluation demonstrated that the risks from intentional acts could be reduced to very low levels with the identified security features.” DEIS at 3-434.^{5/}

In sum, nothing in the evaluation of the threat of terrorist activity conducted for the

^{4/} Plaintiffs mistakenly assert that the analysis in the NBAF draft EIS demonstrates the analysis in the LLNL EA is inadequate because the NBAF analysis “assumed that a release of pathogenic matter would occur.” Pls.’ 2nd Supp. Br. at 7. To the contrary, the EA of the BSL-3 also evaluates impacts based on the assumption that a terrorist attack would result in a breach of containment and a release of a pathogen. FREA at 59.

^{5/} The most prominent impacts identified in the draft EIS of NBAF appear to be visual impacts and infrastructure impacts. DEIS at ES-11.

1 NBAF draft EIS suggests the DOE failed to consider relevant factors in the LLNL BSL-3 EA.

2 **3. The Evaluation of Operational Accidents and External Acts in the**
3 **NBAF Draft EIS Does Not Demonstrate DOE Failed to Consider**
4 **Relevant Factors.**

5 Plaintiffs emphasize that the NBAF draft EIS separately evaluates the consequences of
6 operational accidents and external acts and claim that the EA for the LLNL BSL-3 is flawed for
7 failing to make the same distinction. Pls.' 2nd Supp. Br. at 8. Contrary to Plaintiffs'
8 characterization, the EA for the LLNL BSL-3 also separately evaluates operational accidents and
9 external acts. See FREA at 40-46 (discussing human health impacts of lab operations); FREA
10 50-55 (discussing abnormal events and accidents); FREA at 57-66. Plaintiffs' real dispute is
11 with the DOE's conclusion that the reasonably foreseeable impacts of such events are bounded
12 by the same Maximum Credible Event release scenario. See FREA at 51-55 (discussing
13 Maximum Credible Event); id. at 59-60 (discussing applicability of Maximum Credible Event to
14 release caused by terrorist attack). As set forth in briefing already before the Court, the DOE's
15 determination that the Maximum Credible Event scenario appropriately bounded the impacts of
16 both and external event and an operational accident is well-supported by the record before the
17 Court. Opp. to Plfs' Mtn. for Prelim. Inj. [Dkt. No. 11] at 8-10.

18 The fact that DHS found it appropriate to conduct separate bounding analyses for
19 operational accidents and external acts for the NBAF is unremarkable, and certainly does not
20 demonstrate that the DOE's use of a single bounding analysis for both categories of events was
21 arbitrary and capricious. As noted above, the NBAF and the LLNL BSL-3 are vastly different
22 facilities. The fact that DHS would adopt one methodology to address a 500,000 square foot,
23 first of its kind lab with BSL-4 capabilities, does not suggest that DOE erred in choosing to use a
24 slightly different methodology to evaluate a 1,500 square foot BSL-3 lab which is operationally
25 indistinguishable from hundreds of similar facilities nation-wide.

26 The choice of analytical methodology is one left to agency discretion. As the Ninth
27 Circuit recently emphasized in a unanimous *en banc* decision, "NEPA does not require [the
28 reviewing court] to 'decide whether [a NEPA document] is based on the best scientific

methodology available.” Lands Council v. McNair, __ F.3d __, 2008 WL 2640001, at *19 (9th Cir. 2008)*19, quoting Friends of Endangered Species, Inc. v. Jantzen, 760 F.2d 976, 986 (9th Cir. 1985) (citations omitted). The Ninth Circuit emphasized that courts should “conduct a ‘particularly deferential review’ of an ‘agency’s predictive judgments about areas that are within the agency’s field of discretion and expertise . . . as long as they are reasonable.” Id. at *9, quoting Earthlink, Inc. v. FCC, 462 F.3d 1, 12 (D.C. Cir. 2006) (citations and internal quotations omitted).

Here, the DOE has explained, based on the administrative record, why its bounding analysis is reasonable. The different bounding analysis used by the DHS in the draft EIS for the NBAF does not suggest the DOE failed to consider any relevant factors in the LLNL BSL-3 EA.

4. The Inclusion of Mitigated and Unmitigated Scenarios in the NBAF Draft EIS Does Not Demonstrate DOE Failed to Consider Relevant Factors.

Plaintiffs also claim that the NBAF draft EIS demonstrates that the LLNL BSL-3 EA is inadequate because it did not consider both “mitigated and unmitigated scenarios” for a release occurring as the result of an accident or terrorist attack. Pls.’ 2nd Supp. Br. at 9. This claim fails.

In the NBAF draft EIS, the DHS developed both unmitigated scenarios, which are accidents “evaluated without primary or secondary biocontainment barriers or procedural controls in place,” DEIS at 3-374, and mitigated scenarios, which assume a “facility that has been appropriately designed, constructed, and operated to handle the high-containment pathogens proposed for study in the NBAF.” DEIS at E-11. The EA for the LLNL BSL-3 developed accident scenarios based on a reasonably foreseeable impacts analysis that included the mitigating effects of the facility’s operational controls. FREA at 54-55 (accident analysis assumes HEPA filters work, but for conservative results, that they work below normal efficiency).^{6/}

^{6/} Although Plaintiffs have never previously alleged that the DOE erred in considering mitigated impacts in the LLNL BSL-3 EA, it is well established that an agency may use

1 While Plaintiffs might prefer an analysis that includes only unmitigated scenarios, such
 2 an approach is simply not required by NEPA. NEPA requires an agency to disclose the
 3 “reasonably foreseeable” impacts of a proposed action, not to speculate over unmitigated worse
 4 case scenarios. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 356 (1989)
 5 (upholding CEQ’s decision to remove a “worst case analysis” requirement from the NEPA
 6 regulations, and noting that by “requiring that an EIS focus on reasonably foreseeable impacts,
 7 the new regulation ‘will generate information and discussion on those consequences of greatest
 8 concern to the public and of greatest relevance to the agency’s decision,’ rather than distorting
 9 the decisionmaking process by overemphasizing highly speculative harms.”) (citations omitted).

10 The DOE disclosed the reasonably foreseeable impacts of the LLNL BSL-3 facility, and
 11 in so doing fully complied with NEPA. In fact, while the draft EIS for NBAF contains both
 12 unmitigated and mitigated scenarios, the DHS also ultimately concludes that unmitigated impact
 13 scenarios are not reasonably foreseeable and final estimates of the “behavior of the facility under
 14 accident conditions were based on the mitigated accidents, wherein full or partial functionality of
 15 safety control or barrier is assumed.” DEIS at E-6.^{7/}

16 **5. The Draft EIS for the NBAF Does Not Demonstrate the DOE Failed** 17 **to Follow Applicable Standards.**

18 Finally, Plaintiffs assert that the LLNL BSL-3 EA is deficient for failing to utilized two
 19 DOE Standards that were used in the NBAF draft EIS. Pls.’ 2nd Supp. Br. at 10. This claim is

20 mitigated impacts to determine a project has no significant impacts. See, e.g., Churchill County
 21 v. Norton, 276 F.3d 1060, 1080-81 (9th Cir. 2001) (Army Corps could justifiably determine that
 22 mitigation measures render adverse impacts so minor as to not warrant an EIS); Wetlands Action
 23 Network v. U.S. Army Corps of Engineers, 222 F.3d 1105, 1121 (9th Cir. 2000) (decision to
 24 forego issuing an EIS may be justified by presence of mitigating measures even if those
 25 measures do not completely compensate for adverse environmental impacts).

^{7/} DHS appears to have developed the comparison between mitigated and unmitigated
 26 scenarios in part because the NBAF is only “at the conceptual design stage, [so] there is less
 27 detailed information available for developing detailed system interaction models than would
 28 commonly be available with a final design.” DEIS at E-6. In contrast, operational details of the
 EA LLNL were BSL-3 were less speculative at the time the EA was prepared both because the
 facility plan was relatively clear (see FREA at 12-17) and because hundreds of similar facilities
 were already in existence.

baseless.

The first cited standard is DOE Standard 3009-94, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses* (“DOE-STD-3009-94”). As its name suggests, DOE-STD-3009-94, pertains to the preparation of Documented Safety Analyses (“DSAs”) for **nuclear** facilities. Under federal regulations, a DSA must be prepared for certain categories of DOE nuclear facilities. See 10 C.F.R. § 830.204. DOE-STD-3009-94 is designed to guide contractors and others in preparing DSAs that comply with the applicable regulations. See DOE-STD-3009-94 at vi.^{8/} DOE-STD-3009-94 does not set forth any requirements for the content of the NEPA analysis of non-nuclear facilities such as the LLNL BSL-3, and the DOE was not arbitrary and capricious is not utilizing the standard in preparing the LLNL BSL-3 EA.

The second DOE standard identified in the draft EIS for the NBAF is DOE-STD-3014, which sets forth a quantitative approach to assessing the risk of an airplane crash into a hazardous facility.^{9/} In developing the EA for the LLNL BSL-3 facility, rather than conducting the quantitative analysis outlined in DOE-STD-3014, the DOE conducted a qualitative assessment based on the reasoned option of agency experts. See FREA at C-21 to C-23. Contrary to Plaintiffs’ suggestion, nothing in DOE’s decision to use a methodology different from that out-lined in DOE-STD-3014 is arbitrary and capricious. As noted above, agencies have considerable discretion to adopt the methodology they deem reasonable under the circumstances, and DOE-STD-3014 itself indicates its use is not required. See DOE-STD-3014 at 1.

Given the vast differences between the facilities in the amount of material potentially placed at risk by an airplane crash it is unsurprising that the agencies would opt to use different

^{8/} DOE-STD-3009-94 is available at:
http://www.hss.energy.gov/NuclearSafety/techstds/standard/std3009/doe-std-3009-94_cn3_3-30-06.pdf

^{9/} DOE-STD-3014-2006 is available at:
<http://www.hss.energy.gov/NuclearSafety/techstds/standard/std3014/std3014.pdf>

analytical methodologies. Both EA and the draft EIS explain that in the event of an airplane crash the material potentially at risk is that which is outside of secure storage at the time of a crash.^{10/} For the NBAF, 30 liters of material is routinely at risk, while for the LLNL BSL-3, less than one liter of material would routinely be at risk.^{11/}

Finally, Plaintiffs' assertion that the DOE was arbitrary in not using the methodology of DOE-STD-3014 in the LLNL BSL-3 EA is belied by the fact that despite the differing methodologies, both agencies came to the same conclusion: both the NBAF DEIS and the BSL-3 EA concluded that the impacts of airplane crash –assuming some functionality of safety features – would have no significant impacts on public health. See FREA at 51; FREA at C-21 to C-23; DEIS at 3-429 (concluding mitigated aircraft accident scenario would be expected to have “negligible” off-site consequences.”) See also DEIS at E-158 (mitigated airplane accident falls in severity category E/D); DEIS at E-46 (defining severity categories).^{12/}

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' second motion for leave to file a supplemental brief must be denied.

Dated this 15th day of August, 2008.

Respectfully submitted,
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/s/ Barclay T. Samford
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^{10/} See DEIS at E-143 (“Any material outside of secure storage (e.g. freezer, transport packaging) is considered susceptible to the impact and available for release.”); FREA at C-22 (“virtually the entire inventory of pathogens in the BSL-3 facility would be contained in 2-mL double containment plastic vials maintained in padlocked freezer/refrigerators”).

^{11/} DEIS at E-151 (single maximum volume considered is 30-L cGMP); FREA at 59 (routine operations would use on very limited quantities of biological agents and only a few possible operation could hypothetically place up to 1 liter quantities of material at risk at any point in time).

^{12/} Moreover, the frequency of such an incident is projected to be less than 1 time in 1 million operating years. DEIS at 3-429 (Accident Frequency $\leq 1 \times 10^{-6}$); E-158 (Frequency Category V); 3-374 (defining frequency categories).

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UNITED STATES DISTRICT COURT
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TRI-VALLEY CARES, MARYLIA KELLEY,)
JANIS KATE TURNER, and)
JEDIDJAH DE VRIES)

Case No. 08-cv-1372-SBA

Plaintiffs,)
)

v.)
)

SECOND DECLARATION
OF ERIC GARD

UNITED STATES DEPARTMENT OF ENERGY,)
NATIONAL NUCLEAR SECURITY)
ADMINISTRATION, LAWRENCE LIVERMORE)
NATIONAL LABORATORY,)

Defendants.)
)
_____)

I, Eric Gard, hereby declare and state as follows:

1. I am the Associate Program Leader for Select Agent Science at Lawrence Livermore National Laboratory (LLNL). I have the responsibility for overseeing research, development, testing and evaluations for biological detection projects here at LLNL. I have a Ph.D. in Chemistry and 15 years of experience as a researcher and program manager working at the interface of biology and chemistry. In the past 10 years I have been working heavily in the area of biological threat detection and have experience working with and managing select agent activities. I have published numerous peer reviewed articles on biological detection.
2. I am familiar with the National Bio and Agro-Defense Facility (NBAF) draft Environmental Impact Statement (EIS) and with plaintiffs' supplemental brief arguing that because the NBAF and the LLNL BSL-3 facility are comparable both should go through the EIS process.
3. The purpose of this declaration is to dispute and correct a point made on page 6 of plaintiffs' supplemental brief which states "both facilities will house similar quantities of pathogenic material and therefore represent similar threats to the environment".
4. Plaintiffs correctly note that the EA for the LLNL BSL-3 facility specifies a maximum inventory of 50 liters of pathogenic material, although I have previously explained that it will be years, if ever, before the LLNL BSL-3 will contain that volume. The plaintiffs assertion that "tens of liters of pathogen-rich solution" represents the overall

inventory of the NBAF facility is based on a misunderstanding of a statement in the NBAF draft EIS (incorrectly cited as pg E-134 but actually on pg E-135) which provides the following: "The source of pathogen would include the cGMP facility considered for operation in the NBAF that is capable of processing tens of liters of pathogen-rich solution. In addition, the NBAF also houses the inventory of infected animals as discussed in previous accident scenarios." The cGMP facility referenced above is short for "current good manufacturing practice" facility where virus will be grown in ~ 30 L batches for vaccine development. The "tens of liters" mentioned above refers to the "single maximum volume considered" which is estimated to be 30 L (page E-132), and represents just a small portion of the cumulative facility inventory as is evident from the statement drawn from the draft EIS.

4. The NBAF draft EIS does not contain an explicit statement regarding the expected inventory capacity of the facility. However, a credible estimate of the expected inventory capacity can be derived from the quantitative information provided in several of the accident scenarios located in Table 3.13.3-1 on page 3-405 of the NBAF EIS.

- Accident scenario #1 (Spill or uncontrolled release of aerosol pathogen) states that 10^{10} viable virions are derived from 100 ml which converts to 10^{11} viable virions per liter. This can be used as the nominal concentration of pathogen per liter of pathogen-rich solution. This is further supported by the following statement from the NBAF EIS on page E-96: "While there are differences between pathogens in relation to the number of particles in a solution or gel media, it is reasonable to assume that approximately 1×10^8 viable virions could be present in a single milliliter of culture media." This converts to 10^{11} viable virions per liter.
- To determine the entire facility capacity, we can use accident scenario #7 (Large multi-room spill as a result of a seismic event) which states that 10^{15} viable virions would be the amount of Material At Risk (MAR).
- To determine the total inventory, divide 10^{15} viable virions by the standard stock concentration of 10^{11} viable virions per liter.

- This results in an inventory capacity of 10^4 liters of material or 10,000 liters which is 200 times larger than the maximum capacity of the LLNL BSL-3 facility.
- Based on this information it is clear that the inventory capacity of NBAF is substantially larger than that for the LLNL BSL-3 facility.

5. The calculation above represents the lower bound of the NBAF maximum inventory based one accident scenario. The NBAF draft EIS (page E-135) contains another accident scenario where the Material at Risk "is assumed to be a significant number of viable pathogens on the order of 1×10^{20} (or greater) that could be available for release in either of the proposed natural phenomena events." Using this as a starting point for the inventory capacity calculation leads to an estimate of the NBAF maximum inventory capacity which is orders of magnitude larger.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

 7/25/08

Dr. Eric E. Gard

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

TRI-VALLEY CARES, MARYLIA KELLEY,
JANIS KATE TURNER, and
JEDIDJAH DE VRIES,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF ENERGY,
NATIONAL NUCLEAR SECURITY
ADMINISTRATION, LAWRENCE LIVERMORE
NATIONAL LABORATORY,

Defendants.

Case No. 08-cv-1372-SBA

**[proposed] ORDER DENYING
PLAINTIFFS' SECOND
MOTION FOR LEAVE TO
FILE A SUPPLEMENTAL
BRIEF**

[Docket No. 47]

I. REQUEST BEFORE THE COURT

Before the Court is Plaintiffs' second motion to file a supplemental brief in support of their motion for a preliminary injunction against operation of the Biosafety Level-3 ("BSL") facility at Lawrence Livermore National Laboratory ("LLNL") at Livermore, California. Dkt. No. 47. In their motion, Plaintiffs seek the admission – as extra-record evidence “necessary to determine whether the agency has considered all relevant factors and has explained its decision,” – of a draft Environmental Impact Statement (“EIS”) issued in June 2008 by the Department of Homeland Security (“DHS”) for a proposed National Bio and Agro-Defense Facility (“NBAF”). As discussed below, the Court DENIES the motion on two independent grounds. First, Plaintiffs' motion fails because the proffered draft EIS was not available to the DOE at the time the BSL-3 decision was made, and post-decision materials are not admissible extra-record evidence of factors an agency allegedly failed to consider. Second, assuming arguendo, that post-decision materials are admissible, the draft EIS for the NBAF does not demonstrate that the DOE failed to consider any relevant factors or was otherwise arbitrary or capricious in issuing the EA for the LLNL BSL-3 facility.

II. LEGAL STANDARDS

Judicial review of the adequacy of the BSL-3 EA prepared by the DOE is governed by the Administrative Procedure Act (“APA”), 5 U.S.C. § 706. Under the APA, a court is to review an agency’s decision on the basis of the administrative record that existed before the agency at the time the decision was made. Both the Supreme Court and the Ninth Circuit have emphasized that “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” Camp v. Pitts, 411 U.S. 138, 142 (1973). See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985); Southwest Ctr. for Biological Diversity v. U.S. Forest Serv., 100 F.3d 1443, 1450 (9th Cir. 1996). As the Ninth Circuit has held, “[t]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.” Friends of the Earth v. Hintz, 800 F.2d 822, 829 (9th Cir. 1986) (quoting Florida Power & Light Co., 470 U.S. at 743-44); see Southwest Ctr. for Biological Diversity, 100 F.3d at 1450-51.

If the record is not sufficient to judge the agency’s decision, the decision should be remanded. Courts are not to consider information “that was not available at the time the [Agency] made its decision.” Airport Cmty. Coalition v. Graves, 280 F. Supp.2d 1207, 1213 (W.D. Wash. 2003) (noting that consideration of “new information represents ‘Monday morning quarterbacking.’”).

The Ninth Circuit allows a reviewing court to consider extra-record materials in APA cases only under four narrow exceptions: “(1) if necessary to determine ‘whether the agency has considered all relevant factors and explained its decision,’ (2) ‘when the agency has relied on documents not in the record,’ (3) ‘when supplementing the record is necessary to explain technical terms or complex subject matter,’” or (4) “‘when plaintiffs make a showing of agency bad faith.’” Inland Empire Public Lands Council v. Glickman, 88 F.3d 697, 703-04 (9th Cir. 1996) (quoting Friends of the Payette v. Horseshoe Bend Hydroelectric Co., 988 F.2d 989, 997 (9th Cir. 1993) (per curiam) and National Audubon Soc’y v. U.S. Forest Serv., 46 F.3d 1437, 1447 n.9 (9th Cir. 1993)).

1 Mere allegations that the court should look beyond the administrative record to consider
 2 material falling into one of the four exceptions are not sufficient; a plaintiff must first make a
 3 showing that the record is inadequate. Animal Defense Council v. Hodel, 840 F.2d 1432, 1437
 4 (9th Cir. 1988) (“The [plaintiff] makes no showing that the district court *needed* to go outside the
 5 administrative record to determine whether the [agency] ignored information”) (emphasis
 6 added).

7 **III. ANALYSIS**

8 For the following two separate and independent reasons, the Court DENIES Plaintiffs’
 9 motion.

10 **A. The Draft EIS for the NBAF Does Not Fall Within Any Exception to Record** 11 **Review.**

12 The Ninth Circuit recognizes four limited exceptions to the rule that the review of an
 13 agency action is limited to the administrative record. Plaintiffs assert that the NBAF draft EIS is
 14 admissible under the exception for materials necessary to determine “whether the agency has
 15 considered all relevant factors and explained its decision.” Pls.’ 2nd Mot. for Leave at 3. This
 16 claim fails at the threshold because the exception allowing admission of extra-record material to
 17 determine whether the agency has considered all relevant factors and explained its decision,
 18 “only applies to information available at the time, not post-decisional information.” Rock Creek
 19 Alliance v. U.S. Fish and Wildlife Serv., 390 F. Supp. 2d 993, 1002 (D. Mont. 2005) (denying
 20 motion to submit extra-record material unavailable when the decision was made).

21 As the court in Airport Communities Coalition, 280 F. Supp. 2d at 1213, explained in
 22 striking extra-record material unavailable to the agency when the decision was made:

23 Here the extra-record information represents new information that was not
 24 available at the time the [agency] made its decision. If the information had been
 25 available within that time frame, the court could then use that information to
 26 determine whether the [agency] acted arbitrarily and capriciously in not
 27 considering that information as a relevant factor . . . If the court were to consider
 28 this new information in an arbitrary and capricious analysis the court would
 effectively transform that analysis into a *de novo* review, a level of review for
 which this court is not authorized.

Here, the final revised EA for the LLNL BSL-3 facility was issued on January 25, 2008.

1 Defs' Exh. 5 [Dkt. No. 12] at ¶ 3. The draft EIS for NBAF was issued six months later, in June
 2 2008. The draft EIS for the NBAF was therefore not available for consideration by the DOE
 3 during the decisionmaking process for the LLNL EA, and consequently does not fall within any
 4 exception to record review. For this reason alone, Plaintiffs' motion to file a supplemental brief
 5 is denied.

6 **B. Even if Post-Decision Documents are Admissible, the Draft EIS for NBAF**
 7 **Does Not Show DOE Failed to Consider Relevant Factors or Explain its**
 8 **Decision.**

9 Even assuming documents unavailable to the agency at the time the challenged decision
 10 was made may fall within an exception to record review, for the reasons set forth below, the
 11 Court finds that the NBAF draft EIS does not show DOE failed to consider relevant factors or
 12 explain its decision.

13 **1. The Proposed NBAF and the LLNL BSL-3 are Not Comparable**
 14 **Facilities.**

15 Plaintiffs first assert that because of the "structural and operational similarities" and "like
 16 potential for significant impacts," of the two facilities, the fact that an EIS was prepared for the
 17 proposed NBAF suggests an EIS should also have been prepared for the LLNL BSL-3.

18 Defendants have demonstrated that there is little structural commonality between the two
 19 facilities. The proposed NBAF facility is a complex composed of six buildings encompassing
 20 500,000 to 520,000 square feet and requiring 30-acres of open land. DEIS at ES-3 and 1-2.^{1/} In
 21 contrast, the LLNL BSL-3 is single 1,500 square foot building constructed on 1/4 quarter acre of
 22 land. FREA at 9. The proposed NBAF includes a staff of 250-350 people, while the LLNL
 23 BSL-3 lab has a staff of six. Compare DEIS at 1-2 with FREA at 9. NBAF could house 200 to
 24 300 large animals at any given time, including cattle, swine and sheep, while the BSL-3 has the
 25 capacity of contain a maximum of 100 small rodents. Compare DEIS at 2-1 with FREA at 16.

Obviously, two such vastly different facilities will have substantially different impacts.

26 ^{1/} The Court will cite to the Draft EIS for the NBAF, which is Exhibit 30 to Docket
 27 Numbers 47-49, as "DEIS" followed by the appropriate page. The Court will cite the Final
 28 Revised EA for the LLNL BSL-3, which is Exhibit 1 to Dkt. No. 12, as "FREA" followed by
 the appropriate page.

1 For example, the draft EIS for NBAF anticipates that the facility will generate 25 to 30 million
2 gallons of wastewater annually, while the LLNL BSL-3 is anticipated to generate 10,000 gallons.
3 Compare DEIS at ES-7 with FREA at 24. Moreover the NBAF, which would be similar in size
4 to a 400 bed hospital or 1,600 student high school, would have unavoidable adverse visual
5 impacts. DEIS at ES-7. In contrast, the LLNL BSL-3 occupies a former parking lot and has “no
6 visual issues.” FREA at 31. These differences easily justify the preparation of an EIS in one
7 case and an EA in the other.

8 The Court finds there is little “operational similarity” between the two facilities. Most
9 critically, the NBAF will include between 55,000 and 57,000 square feet designed for BSL-4
10 research. DEIS at 1-2 (“Approximately 11% of the 500,000 to 520,000-square-foot NBAF
11 would be designed for BSL-4 research...”). Unlike a BSL-3 facility, which utilizes pathogens for
12 which medical treatment is available, BSL-4 facilities are equipped to handle “exotic pathogens
13 that pose a high risk of life threatening disease in animals or humans through the aerosol route
14 and for which *there is no known vaccine or therapy.*” DEIS at 1-2 (emphasis added). The
15 presence of a BSL-4 capability alone is a critical difference between the two facilities from a
16 NEPA perspective. As explained in the NBAF draft EIS, while there are 1,356 BSL-3 facilities
17 in 46 states, there are only 15 planned, under construction or operational BSL-4 labs nation-
18 wide. DEIS at 1-3. Further, once constructed, the NBAF will be the *only* large animal or
19 livestock BSL-4 facility in the United States. DEIS at 1-3.

20 Plaintiffs’ suggestion that the two facilities will work with similar types and volumes of
21 pathogens is also baseless. Pls.’ 2nd Supp. Br. at 6. The NBAF is proposed to “enable basic and
22 advanced research, diagnostic testing and validation, countermeasure development (i.e. vaccines
23 and antiviral therapies), and diagnostic training for high-consequence livestock diseases with
24 potentially devastating impacts to U.S. agriculture and public health.” DEIS at ES-1. In pursuit
25 of that mission, NBAF will focus on zoonotic (capable of animal to human transmission) and
26 foreign animal diseases, including African swine fever, classical swine fever, foot and mouth
27 disease (“FMD”), Japanese encephalitis, Rift Valley fever and the Hendra and Nipah viruses,
28 DEIS at 1-2, none of which are expected to be cultured at the LLNL BSL-3. One of the principal

missions of the NBAF is development of a vaccine for FMD, which “is one of the most devastating viral animal diseases affecting cloven hoofed animals.” DEIS at 1-4. The mission of the LLNL BSL-3, in contrast, targets the reduction of the national threat from terrorism using biological weapons and enhancement of public health capabilities. FREA at 6.

Plaintiffs also erroneously assert that the LLNL BSL-3 facility holds the same volume of pathogenic material, “concentrated in a smaller area,” as NBAF. Pls.’ 2d Supp. Br. at 6, n. 3. While the NBAF draft EIS does not explicitly set forth the maximum volume of pathogenic material contained facility-wide, the quantity of material at risk used in the NBAF accident analysis suggests a total facility volume of approximately **10,000 liters** – approximately 200 times the capacity of the LLNL BSL-3 facility.

In sum, the NBAF facility is vastly larger than the LLNL BSL-3, works with a vastly larger volume of different and higher risk pathogens than the LLNL BSL-3 facility, and serves a different purpose than the BSL-3 facility. Moreover, rather than one of over a thousand similar facilities nation-wide like the LLNL BSL-3, the NBAF is the first of its kind in the United States. Under these circumstances, the decision to prepare an EIS for the NBAF does not suggest that DOE was arbitrary and capricious in its decision not to prepare an EIS for the LLNL BSL-3.

2. The NBAF EIS Does Not Suggest the DOE Failed to Consider Relevant Factors in Evaluating the Threat of Terrorist Activity.

The Court also finds Plaintiffs’ claim that the draft EIS for the NBAF demonstrates that the DOE failed to take a “hard look” at the potential environmental consequences of a terrorist attack at the proposed BSL-3 facility to be unpersuasive.

First, as noted above, the NBAF and the LLNL BSL-3 are not comparable facilities, and for that reason, the methodology utilized in one analysis does not suggest that the methodology for the other analysis was inappropriate. For example, the LLNL BSL-3 adds one facility to a baseline of hundreds of facilities nation-wide, and thus makes a negligible incremental change in the risk of a terrorist attack. See FREA at 63. In contrast, the NBAF is the only facility of its kind, and thus the difference between action and no-action is more likely meaningful.

1 However, to the extent that any comparison is appropriate, the terrorist analysis
 2 conducted by the DHS for the NBAF is similar to that prepared for the LLNL BSL-3. For
 3 example, the DHS developed a Threat and Risk Assessment (“TRA”) to “identify potential
 4 vulnerabilities and weaknesses . . . and . . . recommend the most prudent measures to establish a
 5 reasonable level of risk for the security of operations fo the NBAF.” DEIS at 3-430. Similarly,
 6 for the LLNL lab, the DOE developed a Biological Risk and Treat Assessment (“BRTA”) to
 7 “examine the potential vulnerabilities of the facility and its operations, and to mitigate risks.”
 8 FREA at 61. Both the TRA for NBAF and the LLNL EA consider threats of external acts and
 9 internal sabotage. Compare DEIS at 3-341 with FREA at 58. The NBAF TRA addressed
 10 mitigating threats through measures such as personnel security programs, contractor screening
 11 and monitoring, perimeter security procedures, behavior observation programs, inventory
 12 control, and coordination with local emergency response agencies. DEIS at 3-433. The EA for
 13 LLNL discussed analogous mechanisms for mitigating threats to the BSL-3 lab. See FREA at 63
 14 (discussing “personnel security and screening programs”); id. at 61 (discussing perimeter
 15 security), id. at 65 (discussing personnel and inventory monitoring); id. at 60 (discussing
 16 coordination with local medical providers). In sum, the analytical approaches taken for the two
 17 documents are quite similar.^{2/}

18 Finally, with regard to the Ninth Circuit’s direction on remand, that the DOE “consider
 19 whether the threat of terrorist activity necessitates the preparation of an Environmental Impact
 20 Statement,” the draft EIS for NBAF supports the DOE’s conclusion that the threat of terrorist
 21 activities does not have significant impacts requiring an EIS. Tri-Valley CARES v. Dep’t of
 22 Energy, No. 04-17252, 2006 WL 2971651, at *2 (9th Cir. Oct. 16, 2006). While the DHS has
 23 prepared an EIS, that analysis was not compelled by the impacts of potential terrorist activities.

24
 25
 26 ^{2/} Plaintiffs mistakenly assert that the analysis in the NBAF draft EIS demonstrates the
 27 analysis in the LLNL EA is inadequate because the NBAF analysis “assumed that a release of
 28 pathogenic matter would occur.” Pls.’ 2nd Supp. Br. at 7. To the contrary, the EA of the BSL-3
 also evaluates impacts based on the assumption that a terrorist attack would result in a breach of
 containment and a release of a pathogen. FREA at 59.

1 To the contrary, the draft EIS concludes that “[t]he evaluation demonstrated that the risks from
 2 intentional acts could be reduced to very low levels with the identified security features.” DEIS
 3 at 3-434.^{3/}

4 In sum, the Court concludes that nothing in the evaluation of the threat of terrorist
 5 activity conducted for the NBAF draft EIS suggests the DOE failed to consider relevant factors
 6 in the LLNL BSL-3 EA.

7
 8 **3. The Evaluation of Operational Accidents and External Acts in the**
 9 **NBAF Draft EIS Does Not Demonstrate DOE Failed to Consider**
 10 **Relevant Factors.**

11 Plaintiffs emphasize that the NBAF draft EIS separately evaluates the consequences of
 12 operational accidents and external acts and claim that the EA for the LLNL BSL-3 is flawed for
 13 failing to make the same distinction. Pls.’ 2nd Supp. Br. at 8. Contrary to Plaintiffs’
 14 characterization, the EA for the LLNL BSL-3 also separately evaluates operational accidents and
 15 external acts. See FREA at 40-46 (discussing human health impacts of lab operations); FREA
 16 50-55 (discussing abnormal events and accidents); FREA at 57-66. Plaintiffs’ real dispute is
 17 with the DOE’s conclusion that the reasonably foreseeable impacts of such events are bounded
 18 by the same Maximum Credible Event release scenario. See FREA at 51-55 (discussing
 19 Maximum Credible Event); id. at 59-60 (discussing applicability of Maximum Credible Event to
 20 release caused by terrorist attack). Briefing already before the Court, see Opp. to Plfs’ Mtn. for
 21 Prelim. Inj. [Dkt. No. 11] at 8-10, explains DOE’s determination that the Maximum Credible
 22 Event scenario appropriately bounded the impacts of both and external event and an operational
 23 accident and the NBAF draft EIS is unnecessary to review of that determination.

24 The fact that DHS found it appropriate to conduct separate bounding analyses for
 25 operational accidents and external acts for the NBAF is unremarkable, and certainly does not
 26 demonstrate that the DOE’s use of a single bounding analysis for both categories of events was
 27 arbitrary and capricious. As noted above, the NBAF and the LLNL BSL-3 are vastly different

28 ^{3/} The most prominent impacts identified in the draft EIS of NBAF appear to be visual
 impacts and infrastructure impacts. DEIS at ES-11.

1 facilities. The fact that DHS would adopt one methodology to address a 500,000 square foot,
 2 first of its kind lab with BSL-4 capabilities, does not suggest that DOE erred in choosing to use a
 3 slightly different methodology to evaluate a 1,500 square foot BSL-3 lab which is operationally
 4 indistinguishable from hundreds of similar facilities nation-wide.

5 The choice of analytical methodology is one left to agency discretion. As the Ninth
 6 Circuit recently emphasized in a unanimous *en banc* decision, “NEPA does not require [the
 7 reviewing court] to ‘decide whether [a NEPA document] is based on the best scientific
 8 methodology available.’” Lands Council v. McNair, __ F.3d __, 2008 WL 2640001, at *19 (9th
 9 Cir. 2008)*19, quoting Friends of Endangered Species, Inc. v. Jantzen, 760 F.2d 976, 986 (9th
 10 Cir. 1985) (citations omitted). The Ninth Circuit emphasized that courts should “conduct a
 11 ‘particularly deferential review’ of an ‘agency’s predictive judgments about areas that are within
 12 the agency’s field of discretion and expertise . . . as long as they are reasonable.” Id. at *9,
 13 quoting Earthlink, Inc. v. FCC, 462 F.3d 1, 12 (D.C. Cir. 2006) (citations and internal quotations
 14 omitted).

15 Here, the DOE has explained, based on the administrative record, why its bounding
 16 analysis is reasonable. The different bounding analysis used by the DHS in the draft EIS for the
 17 NBAF does not suggest the DOE failed to consider any relevant factors in the LLNL BSL-3 EA.

18 **4. The Inclusion of Mitigated and Unmitigated Scenarios in the NBAF**
 19 **Draft EIS Does Not Demonstrate DOE Failed to Consider Relevant**
 20 **Factors.**

21 The Court has considered and rejects Plaintiffs’ claim that the NBAF draft EIS
 22 demonstrates that the LLNL BSL-3 EA is inadequate because it did not consider both “mitigated
 23 and unmitigated scenarios” for a release occurring as the result of an accident or terrorist attack.
 24 Pls.’ 2nd Supp. Br. at 9.

25 In the NBAF draft EIS, the DHS developed both unmitigated scenarios, which are
 26 accidents “evaluated without primary or secondary biocontainment barriers or procedural
 27 controls in place,” DEIS at 3-374, and mitigated scenarios, which assume a “facility that has
 28 been appropriately designed, constructed, and operated to handle the high-containment

1 pathogens proposed for study in the NBAF.” DEIS at E-11. The EA for the LLNL BSL-3
 2 developed accident scenarios based on a reasonably foreseeable impacts analysis that included
 3 the mitigating effects of the facility’s operational controls. FREA at 54-55 (accident analysis
 4 assumes HEPA filters work, but for conservative results, that they work below normal
 5 efficiency).^{4/}

6 While Plaintiffs might prefer an analysis that includes only unmitigated scenarios, such
 7 an approach is simply not required by NEPA. NEPA requires an agency to disclose the
 8 “reasonably foreseeable” impacts of a proposed action, not to speculate over unmitigated worse
 9 case scenarios. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 356 (1989)
 10 (upholding CEQ’s decision to remove a “worst case analysis” requirement from the NEPA
 11 regulations, and noting that by “requiring that an EIS focus on reasonably foreseeable impacts,
 12 the new regulation ‘will generate information and discussion on those consequences of greatest
 13 concern to the public and of greatest relevance to the agency’s decision,’ rather than distorting
 14 the decisionmaking process by overemphasizing highly speculative harms.”) (citations omitted).

15 The DOE disclosed the reasonably foreseeable impacts of the LLNL BSL-3 facility, and
 16 in so doing fully complied with NEPA. In fact, while the draft EIS for NBAF contains both
 17 unmitigated and mitigated scenarios, the DHS also ultimately concludes that unmitigated impact
 18 scenarios are not reasonably foreseeable and final estimates of the “behavior of the facility under
 19 accident conditions were based on the mitigated accidents, wherein full or partial functionality of
 20 safety control or barrier is assumed.” DEIS at E-6.

21 **5. The Draft EIS for the NBAF Does Not Demonstrate the DOE Failed** 22 **to Follow Applicable Standards.**

23
 24 ^{4/} Although Plaintiffs have never previously alleged that the DOE erred in considering
 25 mitigated impacts in the LLNL BSL-3 EA, it is well established that an agency may use
 26 mitigated impacts to determine a project has no significant impacts. See, e.g., Churchill County
 27 v. Norton, 276 F.3d 1060, 1080-81 (9th Cir. 2001) (Army Corps could justifiably determine that
 28 mitigation measures render adverse impacts so minor as to not warrant an EIS); Wetlands Action
Network v. U.S. Army Corps of Engineers, 222 F.3d 1105, 1121 (9th Cir. 2000) (decision to
 forego issuing an EIS may be justified by presence of mitigating measures even if those
 measures do not completely compensate for adverse environmental impacts).

1 Finally, the Court finds unpersuasive Plaintiffs assert that the LLNL BSL-3 EA is
 2 deficient for failing to utilized two DOE Standards that were used in the NBAF draft EIS. Pls.’
 3 2nd Supp. Br. at 10.

4 The first cited standard is DOE Standard 3009-94, *Preparation Guide for U.S.*
 5 *Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses* (“DOE-STD-
 6 3009-94”). As its name suggests, DOE-STD-3009-94, pertains to the preparation of
 7 Documented Safety Analyses (“DSAs”) for **nuclear** facilities. Under federal regulations, a DSA
 8 must be prepared for certain categories of DOE nuclear facilities. See 10 C.F.R. § 830.204.
 9 DOE-STD-3009-94 is designed to guide contractors and others in preparing DSAs that comply
 10 with the applicable regulations. See DOE-STD-3009-94 at vi.^{5/} DOE-STD-3009-94 does not set
 11 forth any requirements for the content of the NEPA analysis of non-nuclear facilities such as the
 12 LLNL BSL-3, and the DOE was not arbitrary and capricious is not utilizing the standard in
 13 preparing the LLNL BSL-3 EA.

14 The second DOE standard identified in the draft EIS for the NBAF is DOE-STD-3014,
 15 which sets forth a quantitative approach to assessing the risk of an airplane crash into a
 16 hazardous facility.^{6/} In developing the EA for the LLNL BSL-3 facility, rather than conducting
 17 the quantitative analysis outlined in DOE-STD-3014, the DOE conducted a qualitative
 18 assessment based on the reasoned option of agency experts. See FREA at C-21 to C-23.
 19 Nothing in DOE’s decision to use a methodology different from that out-lined in DOE-STD-
 20 3014 is arbitrary and capricious. As noted above, agencies have considerable discretion to adopt
 21 the methodology they deem reasonable under the circumstances, and DOE-STD-3014 itself
 22 indicates its use is not required. See DOE-STD-3014 at 1.

23 Given the vast differences between the facilities in the amount of material potentially
 24

25 ^{5/} DOE-STD-3009-94 is available at:
 26 http://www.hss.energy.gov/NuclearSafety/techstds/standard/std3009/doe-std-3009-94_cn3_3-30-06.pdf

27 ^{6/} DOE-STD-3014-2006 is available at:
 28 <http://www.hss.energy.gov/NuclearSafety/techstds/standard/std3014/std3014.pdf>

placed at risk by an airplane crash it is unsurprising that the agencies would opt to use different analytical methodologies. Both EA and the draft EIS explain that in the event of an airplane crash the material potentially at risk is that which is outside of secure storage at the time of a crash.^{7/} For the NBAF, 30 liters of material is routinely at risk, while for the LLNL BSL-3, less than one liter of material would routinely be at risk.^{8/}

Finally, Plaintiffs' assertion that the DOE was arbitrary in not using the methodology of DOE-STD-3014 in the LLNL BSL-3 EA is belied by the fact that despite the differing methodologies, both agencies came to the same conclusion: both the NBAF DEIS and the BSL-3 EA concluded that the impacts of airplane crash –assuming some functionality of safety features – would have no significant impacts on public health. See FREA at 51; FREA at C-21 to C-23; DEIS at 3-429 (concluding mitigated aircraft accident scenario would be expected to have “negligible” off-site consequences.”) See also DEIS at E-158 (mitigated airplane accident falls in severity category E/D); DEIS at E-46 (defining severity categories).^{9/}

IV. CONCLUSION

Accordingly, the Court DENIES Plaintiffs' Second Motion for Leave to File a Supplemental Brief [Dkt. No. 47].

IT IS SO ORDERED.

^{7/} See DEIS at E-143 (“Any material outside of secure storage (e.g. freezer, transport packaging) is considered susceptible to the impact and available for release.”); FREA at C-22 (“virtually the entire inventory of pathogens in the BSL-3 facility would be contained in 2-mL double containment plastic vials maintained in padlocked freezer/refrigerators”).

^{8/} DEIS at E-151 (single maximum volume considered is 30-L cGMP); FREA at 59 (routine operations would use on very limited quantities of biological agents and only a few possible operation could hypothetically place up to 1 liter quantities of material at risk at any point in time).

^{9/} Moreover, the frequency of such an incident is projected to be less than 1 time in 1 million operating years. DEIS at 3-429 (Accident Frequency $\leq 1 \times 10^{-6}$); E-158 (Frequency Category V); 3-374 (defining frequency categories).

September ____, 2008

Saundra Brown Armstrong
United States District Judge